Exhibit 9

Archived: Tuesday, August 8, 2023 8:47:30 AM
From: Rhoad, Robert
To: 'Peterka, James'
Subject: RE: Varenicline
Importance: Normal
Sensitivity: None
Attachments:
~WRD0616.jpg; 2023-06-21 Ltr Par to Zydus re Varenicline.pdf; Varencline -- Par - Zydus Non-Disclosure Agreement (6-21-23).pdf;

Jim,

Thanks for your email. Please see the attached letter and accompanying enclosure.

Regards,

Bob

Robert D. Rhoad

Dechert LLP
A Pennsylvania Limited Liability Partnership
+1 609 955 3269 Direct
robert.rhoad@dechert.com
dechert.com

From: Peterka, James <JPeterka@lockelord.com>
Sent: Wednesday, June 21, 2023 12:27 PM
To: Rhoad, Robert <robert.rhoad@dechert.com>
Subject: Varenicline

[EXTERNAL EMAIL]

Robert,

We represent Zydus in connection with your May 17 and June 9, 2023 letters. We are considering your letters and will respond in due course.

Regards,

Jim

James T. Peterka

Locke Lord LLP

111 S. Wacker Drive

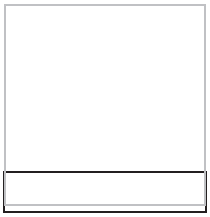
Chicago, IL 60606

312-443-0270 Direct

312-896-6270 Fax

jpeterka@lockelord.com

View My **BIO** I Connect on **LinkedIn** I Visit **lockelord.com**



Dechert LLP

Cira Centre
2929 Arch Street
Philadelphia, PA 19104-2808
+1 215 994 4000 Main
+1 215 994 2222 Fax
www.dechert.com

ROBERT RHOAD

robert.rhoad@dechert.com
+1 609 955 3269 Direct
+1 609 873 9142 Fax

June 21, 2023

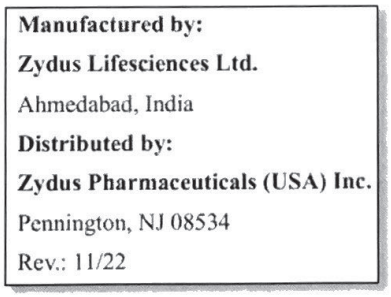
VIA EMAIL
James T. Peterka
Locke Lord LLP
111 S. Wacker Drive
Chicago, IL 60606

RE: Zydus's Varenicline Tartrate Products

Dear James:

Thank you for your email from earlier today stating that you represent Zydus in connection with our prior letters to Zydus on behalf of Par, dated May 17 and June 9, 2023. We write to follow-up on those letters in light of recent developments.

In particular, Zydus announced on June 13th that it received final approval from the United States Food and Drug Administration ("FDA") to manufacture and market varenicline tablets in 0.5 mg and 1 mg dosage strengths, and Par has now obtained a copy of the approved label for those products. Zydus further announced that its products will be manufactured at its facility in Ahmedabad SEZ, India and will be launched in the U.S. shortly. The label indicates that they will be made by Zydus Lifesciences and distributed by Zydus Pharmaceuticals (USA) Inc.:


Manufactured by:
Zydus Lifesciences Ltd.
Ahmedabad, India
Distributed by:
Zydus Pharmaceuticals (USA) Inc.
Pennington, NJ 08534
Rev.: 11/22

Our prior letters notified Zydus of Par's issued and allowed patent claims covering varenicline tartrate tablets and compositions. Par believes it is highly likely that Zydus's now-approved varenicline products infringe upon Par's patent rights, including without limitation, the following allowed claim of Par's U.S. Patent Application No. 17/930,824 (the "'824 application"):

1. A method of making a varenicline tartrate tablet comprising less than 50 ppm of nitrosamine impurities, the method comprising:

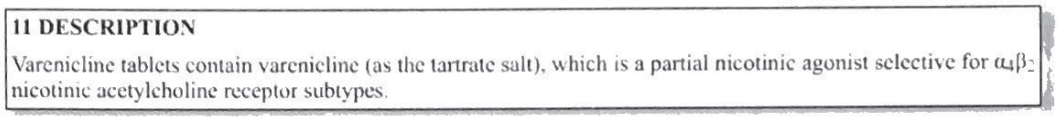
(a) mixing varenicline free base with tartaric acid to form varenicline tartrate; and

(b) means for reducing the nitrosamine impurities to less than 50 ppm per tablet as measured by LC-ESI-HRMS Method;

wherein the means comprises an acid-base treatment.

The basis for Par's belief in that regard is that, among other things:

- The approved label confirms that the active pharmaceutical ingredient ("API") in Zydus's tablets is varenicline tartrate, as claimed:



11 DESCRIPTION

Varenicline tablets contain varenicline (as the tartrate salt), which is a partial nicotinic agonist selective for $\alpha_4\beta_2$ nicotinic acetylcholine receptor subtypes.

- We also know that Zydus's tablets will contain less than 50 ppm of nitrosamine impurities, as claimed, because the FDA's acceptable intake limit for nitrosamine impurities is only 37 ng per day, which translates to 18.5 ppm. *See, e.g.*, https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-nitrosamine-varenicline-chantix.

- The only commercially-viable methods for making varenicline tartrate tablets with the claimed low levels of nitrosamine impurities that Par is aware of are the methods taught and claimed in the '824 application, such that Par believes it is highly likely that Zydus is using those methods (or an equivalent thereof) to make its products.

In our prior letters, we asked Zydus to provide the basis for any belief it may have that the manufacture and sale of its now-approved varenicline tablets would not infringe claim 1 of the '824 application, or any of Par's other issued and allowed claims. Your email reply did not provide any basis for non-infringement, but said instead that Zydus was considering those letters and would respond in due course. Absent a showing by Zydus of non-infringement, Par presumes that Zydus is using the claimed methods and has no basis to deny infringement.

Par believes that review of the master batch record(s) and/or other documentation describing the processes used to manufacture the API included in Zydus's tablets would confirm Zydus's infringement. To the best of Par's knowledge, that documentation is not

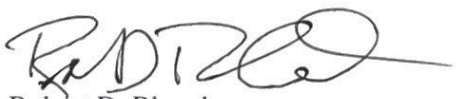
publicly available, but would be contained in the in the CMC sections of Zydus's ANDA and/or in the Drug Master File ("DMF") filed with the FDA for the API.

Accordingly, in order to enable Par to confirm its beliefs as to Zydus's infringement, we ask that Zydus provide us with confidential access to the CMC sections of its ANDA and the DMF for its API, on terms similar to those that are typically provided in Offers of Confidential Access to ANDAs pursuant to 21 U.S.C. § 355(c)(3)(D)(i)(III) and 21 C.F.R. § 314.52(c)(7) ("OCAs"). Although this matter is not subject to those provisions (because Par's varenicline products are not the RLD and because Zydus has already obtained FDA approval), OCAs provide the mechanism by which pharmaceutical companies are able to exchange information necessary to evaluate issues of patent infringement while protecting the confidentiality of the information exchanged, and Zydus undoubtedly has made OCAs in connection with its other generic products. As such, OCAs provide a useful guide that Par believes can be utilized as a basis for a similar exchange of such information in our context. With that in mind, we enclose herewith a proposed Non-Disclosure Agreement which embodies the protections typically included in such OCAs.

Please let us know whether Zydus denies that the launch of its approved varenicline tablets would infringe upon Par's patent rights, and if so, whether Zydus is willing to provide the requested information on a confidential basis pursuant to the terms of the enclosed NDA. If Zydus refuses to provide the requested information, Par will presume that Zydus has no basis to deny that it is utilizing Par's soon-to-be patented manufacturing processes. As you undoubtedly know, the fact that Zydus will manufacture its tablets outside the U.S. will not insulate Zydus from the U.S. patent laws, as Zydus will be liable for infringement, at a minimum, under 35 U.S.C. § 271(g). Moreover, please note that if Zydus refuses to provide the requested information, then in any lawsuit brought by Par to enforce its patent rights, Zydus will have the burden, pursuant to 35 U.S.C. § 295, of establishing that its products are not made in accordance with Par's patented process.

We look forward to Zydus's response.

Sincerely,



Robert D. Rhoad

RDR

Enclosure

NON-DISCLOSURE AGREEMENT

THIS NON-DISCLOSURE AGREEMENT is entered into between Par Pharmaceuticals Inc. ("Par") and Zydus Pharmaceuticals USA Inc. ("Zydus USA") and Zydus Lifesciences Ltd. ("Zydus Lifesciences") (collectively, "Zydus"), and their respective affiliates (collectively, the "Parties"), as of June 21, 2023, and sets forth the terms and conditions pursuant to which Zydus will disclose Confidential Zydus Information (as defined below) to Par for the sole purpose described below (the "Purpose").

WHEREAS Par represents that it owns all right, title, and interest in U.S. Patent No. 11,602,537 ("'537 patent") and U.S. Patent Application No. 17/930,824 (the "'824 application") (collectively, "Par's Varenicline Patents");

WHEREAS Zydus USA represents that it is the holder of Abbreviated New Drug Application No. 216723 (the "Zydus ANDA"), which sought approval of the United States Food and Drug Administration ("FDA") to manufacture and market varenicline tartrate tablets in 0.5 mg and 1 mg dosage strengths ("Zydus Varenicline Products");

WHEREAS the FDA approved the Zydus ANDA on June 12, 2023, and the Zydus Varenicline Products will be manufactured by Zydus Lifesciences and distributed in the United States by Zydus USA;

WHEREAS Zydus wishes to disclose to Par's outside litigation counsel certain confidential information concerning the Zydus Varenicline Products in order to allow Par to evaluate Zydus's contentions that Par's Varenicline Patents do not cover the Zydus Varenicline Products or the processes used to manufacture those products, including information contained in the Zydus ANDA and in the Drug Master File ("DMF") filed with the FDA for the active pharmaceutical ingredient contained in the Zydus Varenicline Products (collectively "Confidential Zydus information"), subject to the terms and conditions set forth in this Non-Disclosure Agreement;

NOW, THEREFORE, THE PARTIES HEREBY AGREE AS FOLLOWS:

1. The term "Confidential Zydus Information" shall include any and all materials, information and know-how disclosed by Zydus to Par's Designated Outside Counsel (defined below), regardless of the form in which it is communicated or maintained, whether oral, electronic, visual, written, stored or in any other form or medium, together with all copies thereof, that are delivered, disclosed or otherwise made accessible by Zydus to Par's Designated Outside Counsel, which may include, without limitation, information relating to Zydus's and third parties' facilities, research, development, analyses, intellectual property, documentation, notes, trade secrets, and products, and all tangible embodiments of such information. The term Confidential Zydus Information shall also include any information derived from the Confidential Zydus Information, and all copies, summaries, and notes of the contents of any part of the Confidential Zydus Information or information derived from the Confidential Zydus Information; provided that information disclosed by Zydus to Par's Designated Outside Counsel shall not be subject to the confidentiality obligations imposed by this Agreement to the extent that Par's Designated Outside Counsel can demonstrate through documentary evidence that:

(1) such information already was lawfully known to Par or Par's Designated Outside Counsel prior to receipt thereof from Zydus; (2) such information was independently developed by Par or Par's Designated Outside Counsel without use of or reference to any Confidential Zydus Information; (3) such information was obtained by Par or Par's Designated Outside Counsel from a third party which had the right to disclose it without any confidentiality obligations; or (4) such information lawfully is or becomes generally known to the public without breach of Par's or Par's Designated Outside Counsel's obligations under this Agreement.

2. Zydus shall disclose Confidential Zydus information to the following attorneys at Dechert LLP: Martin Black, Robert Rhoad, Jonathan Loeb, Brian Goldberg, Sharon Gagliardi, and Daniel Roberts ("Par's Designated Outside Counsel"), who shall use such Confidential Zydus information for the sole and exclusive purpose of determining whether an action for infringement of Par's Varenicline Patents can be brought pursuant to 35 U.S.C. § 271.

3. Par's Designated Outside Counsel shall not engage, formally or informally, in any patent prosecution relating to varenicline or any varenicline-containing products (it being understood that such persons may disclose art for use in prosecution and may participate in post-grant review proceedings, except that they may not be involved directly or indirectly in seeking amendment of any patent claims at issue in any such post-grant review proceedings) for a period of two years after receipt of any Confidential Zydus information or the conclusion of any litigation proceedings between Par and Zydus concerning the Zydus Varenicline Products, whichever is later.

4. Par's Designated Outside Counsel shall not disclose any Confidential Zydus Information to any other person or entity, including without limitation any employees of Par, outside scientific consultants, and/or other outside counsel, without Zydus's prior written consent, and shall not may not make any copies of the Confidential Zydus Information, in whole or in part, for any purpose other than in connection with the Purpose.

5. The Confidential Zydus Information to be disclosed is, and shall remain, the property of Zydus. By providing confidential access to the Confidential Zydus Information, Zydus does not grant Par and/or any of Par's Designated Outside Counsel any interest in or license for the Confidential Zydus Information.

6. Par's Designated Outside Counsel shall, within forty-five (45) days from the last date on which Zydus provides Confidential Zydus Information, destroy or return to Zydus all Confidential Zydus Information received from Zydus and any copies thereof. In the event that Par opts to file a lawsuit for patent infringement, Par's Designated Outside Counsel shall not include any Confidential Zydus Information in any publicly-available complaint or other pleading.

7. Each of Par's Designated Outside Counsel shall acknowledge in writing their receipt of a copy of this Non-Disclosure Agreement prior to the disclosure to them of any Confidential Zydus Information.

8. This Agreement shall be governed by the laws of the State of Delaware. It supersedes any prior agreements and understandings, both written and oral, which may have existed

between the Parties with respect to the subject matter hereof and will not be varied, amended, or supplemented except in a writing signed by both of the Parties. This Agreement may not be assigned by Par, except with the prior written consent of Zydus, and is binding on the successor and assigns of each Party. This Agreement may be executed in one or more counterparts, each of which shall be deemed to be an original, but all of which together shall be considered one and the same instrument.

IN WITNESS WHEREOF, the Parties hereto have executed this Agreement as of the date first written above.

ZYDUS PHARMACEUTICALS USA INC.

_____

Name:

Title:

PAR PHARMACEUTICALS INC.

_____

Name:

Title:

ZYDUS LIFESCIENCES LTD.

_____

Name:

Title: